Short Version

Urs-Vito Albrecht

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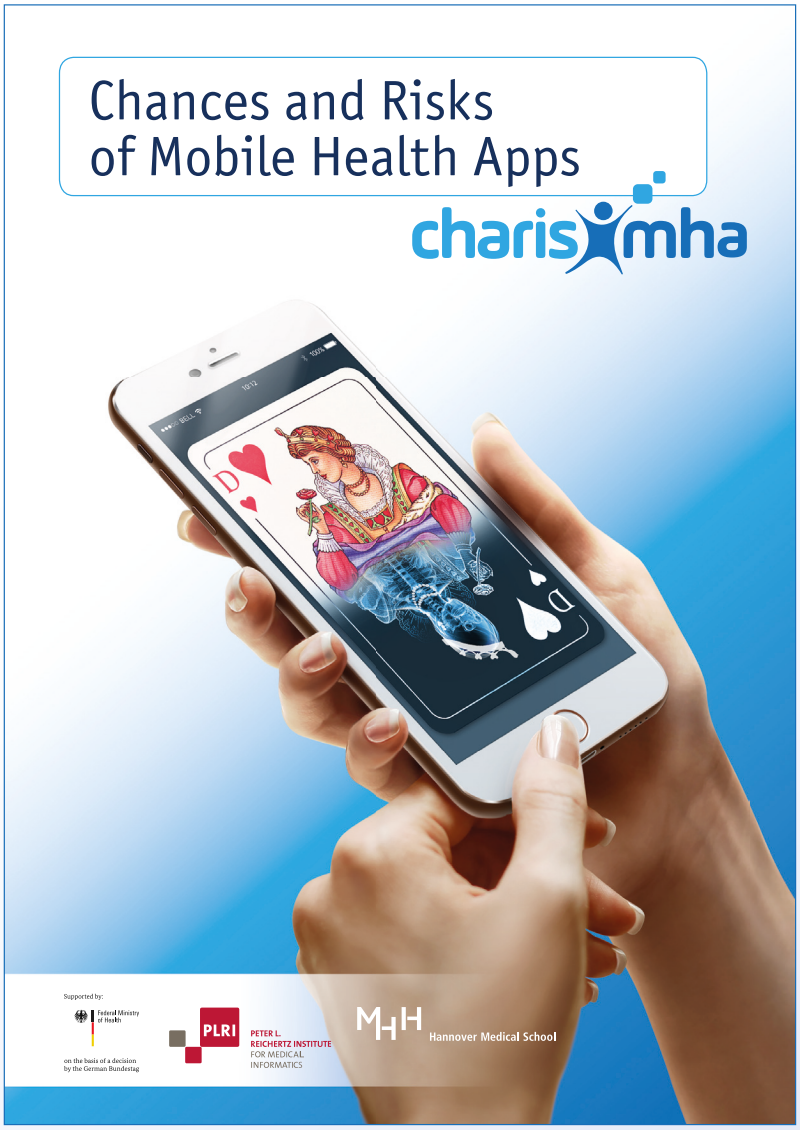

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1 Introduction

1.1 Always There, Immediately Available

See Chapter Rationale. Urs-Vito Albrecht

Mobile technologies integrate seamlessly into our daily lives. They are available in many different forms. Their use characterises our age of accelerated interpersonal communication and information transfer. Nearly a quarter of a century after the presentation of the first multi-functional mobile phones, it is now natural to reach for devices which at the time were considered visionary: smartphones, tablets, smartwatches and data-providing glasses – the range of such products grows as technology becomes increasingly smaller and more networked. The success of portable mini-computers is due to the convenience they offer to fulfil various tasks. Barriers to use are low and the sales and marketing of corresponding software, known as "apps" (short for "applications"), are easy. Providing services supported through mobile technology is now even easier than it was at the beginning of the millennium. This immensely expands the scope for innovation with manageable financial risks for the developers and leads to a wide range – including in the field of health.

Used responsibly, mobile technologies can support the design of modern and equally resource-saving healthcare offerings in the area of medicine. They might even have the potential to contribute to improving the performance and quality of care, especially in the care of chronically ill or elderly persons. Prevention and promotion of health also offer wide areas of application.

Indisputably, there are great opportunities in all of these areas, which are taken up enthusiastically by many. However, the integration of mobile technology into all areas of life also carries a number of risks. Many users turn to the devices with relatively little consideration and are not aware of the potential dangers that can result from using them, especially in highly sensitive areas such as health and medicine.

The present study extensively deals with the issue of the use of mobile technologies in medical and general health-related applications and looks at it from various perspectives. Opportunities and risks are analysed and possible options for action pointed out for all involved. To do this, medical, technical, but also legal, ethical and economic issues are fundamentally analysed. The study deals with the conception, creation and application of mHealth-based solutions and health apps in particular.

1.1.1 Mobile Health (mHealth)

See Chapter 1. Introduction and Definition of Terms[1]. Urs-Vito Albrecht & Ute von Jan

Mobile health, also known as "mHealth" , is a new, dynamic and expanding field of healthcare, which produces innovations in short cycles and is constantly changing. Currently, it is still exploring its own boundaries, meaning that there is still no consensus on a generally applicable definition of the term. Ultimately, mHealth can be understood as healthcare electronically supported by mobile devices.

"mHealth" is closely related to the fields of "telemedicine" and "eHealth" and a clear delimitation is difficult. The fundamental difference is the way in which the corresponding services are provided. "Telemedicine" is often used as a general term to summarise communication technologies (usually-audiovisual). This is understood as a technical bridging of the distance between healthcare professionals and those affected, comprising the spectrum of medical services (diagnostics, consultation, therapy). "eHealth" (also known as "electronic health") is even broader and includes additional health-related services provided by means of modern information and telecommunication technologies. According to the WHO definition, "mHealth" extends the range of functionalities by adding a mobile component. Here, healthcare is provided via any type of mobile device offered, using devices ranging from simple mobile phones through smartphones, phablets and tablets to wearables and other portable devices that can be used in the area of health (Kay, Santos and Takane 2011).

[1] Currently, Chapters 1–15 are only available in German.

1.1.2 Health Apps

The mobile hardware (miniaturised, programmable, performance-optimised and energy-optimised devices) is the basis for apps. This is software that creates countless application possibilities on these devices. Apps turn these devices into specialised tools for specific tasks. "Health apps" are those that are intended for use in health and wellness, but also in the field of medicine. They can be used to prevent or mitigate diseases and their consequences (prevention), but also for providing medical, care and other health related services. They can also support measures that aim at strengthening health (health promotion).

Apps address the entire spectrum of "health" as covered in the WHO's definition of the term. This definition describes health as a "state of complete physical, social and mental well-being and not merely the absence of disease or infirmity" (WHO 1948). Accordingly, "wellness" offerings, whose objective is to improve and strengthen health based on measures aimed at promoting health, also fall under this definition. This is relevant for mHealth. Applications that specifically involve the detection, cure or alleviation of disease, suffering and bodily harm, are attributable to "medicine". This differentiation becomes relevant when an app crosses the boundary between a supporting wellness app and a medical device – with all the resulting consequences for those involved. This will be discussed in greater detail below.

Throughout the report, the previously outlined terms serve as application-related guidance. Due to the rapid developments in the area of mHealth, continuous adjustments and enhancements will be needed. Existing projects and efforts, which serve as a basis for defining terms and performing fundamental research in the context of mHealth on national and international levels, should therefore be encouraged and new ones established where necessary.

1.2 Current Market Situation

1.2.1 Mobile Technology and Its Dissemination

See Chapter 2. Health Apps and Market.
Urs-Vito Albrecht, Matthias Höhn & Ute von Jan

Currently, two companies dominate the mobile operating systems market: Apple with its iOS operating system and Google with Android. At present, these two players hold 97 % of the market, with Android leading the market. The success of these mobile systems is based on the sales and marketing concepts for the software ("app stores"), enabling low-threshold access to the market for both manufacturers and users. This is reflected in the number of apps available. Even if only the two categories "Medicine" and "Health and Fitness" are considered, there are between 80,000 and 90,000 apps, depending on the counting method.

The market for mobile devices is more fragmented. iOS-based devices are developed and distributed exclusively by Apple, while there are numerous manufacturers for the Android system. For Android, manufacturers use a variety of hardware components and customise the operating system to a varying degree. This allows an infinite range of combinations of hardware and software. However, this diversity can also lead to problems if there are different equipment standards and comparisons are difficult.

Those supplying the operating systems deliberately provide only a basic set of functionalities and apps along with their software. The sales model is primarily designed to provide third parties with a platform for their own developments. The corporation also earns money from the distribution of this software, be it by granting licences for the provision of the necessary development environments, a proportion of the proceeds from the sales of apps or indirectly through the sale of equipment.

Manufacturers of health apps come from varied backgrounds. The spectrum of developers and providers ranges from private individuals through privately organised companies and institutions to (health) insurance companies. Within this study, mainly private companies and developers were identified. Public and private health insurance providers, as well as other types of manufacturers and suppliers of apps, for example, public institutions or non-profit organisations, played a relatively minor role.

1.2.2 Economic Aspects

High download rates are only achieved by few apps and their manufacturers. Rarely do the proceeds from the sale of the software cover the costs or allow for a profit. Currently, only few app providers are able to implement viable and profitable business models that are solely based on the sales options (paid apps, in-app purchases, subscriptions) provided by the stores (research2guidance 2015). A following disparity can be observed: Developing an app for the healthcare sector, particularly one of high quality, is expensive. However, customers in the stores are often unwilling to pay substantially more for health-related apps than they would

pay for apps of other categories. In the evaluation carried out in the context of this study, the number of free offers outweighed that of the pay deals by far. Nevertheless, for example, of the free offers available for the Android platform, with between 20 % (category "Medicine") to 40 % (category "Health and Fitness"), only relatively few apps provide in-app purchases (purchase/unlock additional content and features from within the app).

Often, indirect ways of financing the development costs are found, as well as ways of generating profits. These include, among others, providing advertising within the apps. In addition, data can be handled as a "currency", specifically with regard to initially free offers, as proceeds are obtained by selling the data. Both have to be viewed critically, particularly in sensitive areas such as health.

In the long term, financing apps solely through the mechanisms of the stores, which were designed with generic apps in mind, is not economically feasible for all types of applications or manufacturers of apps in the field of medicine and health. Another problem is that, based on this, even for medically useful applications, the burden of financing these applications, rests on the shoulders of the users – apart from some pilot projects funded through health insurance funds/companies and other payers (Terry 2015). Therefore, for the future, it would be desirable to make provisions for mHealth solutions and health apps that have proven their efficacy to make these reimbursable for those who are insured. This could relax the situation for both users and manufacturers and make a significant contribution to the provision of high-quality apps.

1.2.3 User Requirements

According to current figures, 63 % of the German population already use a smartphone, so the number of (potential) users of health apps is large (Weicksel and Pentsi 2015). Their use extends through all layers of the population. The spectrum of users covers various age groups and levels of professionalism, ranging from healthcare professionals with professional demands through those interested in health, to acutely or chronically ill people.

Younger people are more likely to have access to relevant devices than elder people, but the rate of those who use mobile devices and apps (Weicksel and Pentsi 2015) is also increasing among those over the age of 65. Although all these groups can potentially benefit from using health apps, apps for certain user groups were under-represented in our analysis. Only a few apps take into account the needs of physically, mentally or cognitively impaired users. Barrier-free design of an app is something of an exception.

The expansion of funding programmes that support the development of barrier-free and innovative mobile applications could change the landscape of apps being offered. Care should be taken to promote access to mobile technologies in general as well as in the context of health, in particular in certain parts of the population (e.g. the elderly, socially disadvantaged, etc.). This can be done by the provision or partial financing of equipment, training materials, and through appropriate programmes, information campaigns, etc. Equal participation also requires appropriate skills. In the long-term, however, the necessary skills and knowledge should already be part of school education.

1.2.4 Areas of Application and Features Provided

There are health apps available for a wide variety of needs. In the health related sections of the stores, apps of various sub-categories, such as health-related reference books, patient diaries or fitness and wellness apps, are provided. Apps for informational purposes are in the foreground. These include references, teaching and learning materials and news apps. Medical professionals as well as sick people or health conscious users are being addressed. Generally, apps that provide support in health issues play a major role, in particular in the context of chronic diseases.

However, health apps for genuine diagnostic or therapeutic purposes, possibly touching on the area of medical devices, are rare. In the random sample, which was examined in the course of this study, not a single such app of this kind was found.

The expectations and demands placed on health apps vary. Everyone involved has different desires, skills, knowledge and requirements, as well as different ideas about how they should be implemented in a health app. The apps that are tailored to the needs of users of the target group are the successful ones. Thus, these needs must be determined and investigated.

1.2.5 Restricted Market Overview

The market is confusing due to its size, dynamics and little regulated organisation. The monitoring of the market is made more difficult by the lack of transparency on the part of the participating providers (app manufacturers as well as platform operators). Users who want to identify a health app that matches their ideas sometimes struggle when it comes to orientation. There are various reasons for this. In the first place, inadequate or incomprehensible store descriptions (in terms of content and language) that do not provide the particulars of the functionalities and content offered can be confusing. Also, information is often lacking with respect to potential limitations, data protection, or even the manufacturers themselves. In part, this may be due to the fact that to date, on the part of the store owners, the distribution of health apps via the stores is largely subject to the same conditions that must be met for other store categories.

Efforts should be made to make it obligatory for manufacturers to provide information about the content and functionalities of health apps, similar to what the store operators already require in the context of age classifications of apps. Equally, manufacturers should be obliged by the store operators to provide full information on data protection, as well as on the contact data and content of the apps and their sources of funding.

1.3 Political Framework

See Chapter 3. Health Apps and Political Framework.
Urs-Vito Albrecht & Sven Jungmann

According to the European Commission (2015), mHealth – and therefore health apps – have the potential to drive the health sector towards decentralised, patient-centred healthcare which promotes the right to self-determination. mHealth can support European values of solidarity, universality and equality, as well as the European principle of freedom of movement. At the same time, it can stimulate economic growth and support health system innovation.

In this context, the current efforts of the European Commission seem to focus on innovators and decision-makers in order to create an innovation-enabling environment across the EU that is driven by the private sector. Various instruments are employed here, such as public consultations, the development of codes of conduct and guidelines, the promotion of frameworks and standards for interoperability, the revision of the medical device guidelines, and the further development of the consumer protection directives to include digital aspects. By contrast, the German focus appears rather narrow, with an emphasis on strengthening state-managed projects, such as digital discharge records or the electronic health card, which appear technology-centred as opposed to solution-oriented.

Comprehensive efforts are needed to prevent the loss of connection to other nations' eHealth sectors. The digitisation of the German healthcare system is a complex, large-scale project that not only affects healthcare provision, but also research and business. Investments come from both public and private funds. Projects of such a magnitude are prone to frequent and significant budget and deadline overruns, benefit shortfalls, and increased viability risks. This has relevant implications for both Germany's national eHealth strategy and its position as a business location for eHealth companies and health-app manufacturers.

1.3.1 Strategy

One requirement for a fair supply of health apps is the creation of an adequate infrastructure (nationwide coverage with high speed broadband internet) as well as the assurance of a good public digital and health literacy. As future technological developments are difficult to predict (Brynjolfsson and McAfee 2014, Naughton 2012), it is important that Germany develops a robust but adaptable eHealth strategy (Beinhoecker 1999). It should focus on functions and results (e.g. "digitisation of communication"), rather than adhering to certain approaches (e.g. "electronic discharge letter"). Specifically, that means, for example, that financial incentive systems should not only be limited to certain technological approaches, but a stronger focus should be placed on cross-application regulations. Clear rules are also needed for dealing with data that will be collected or processed by apps and mobile devices. As an example, the need for quality standards for applications beyond the Medical Devices Act, the data of which will be used for health-related research, should be mentioned here. Also, the timely development of adapted screening criteria for the application of predictive models based on the user data by apps is required.

1.3.2 Promoting Internationalisation

To take into account the cross-border nature of eHealth and mHealth, a stronger emphasis should be placed on internationalisation. For this purpose, the expertise and the development advantages of internationally-oriented organisations (e.g. ISO, IHE, HL7) would be useful here in order to develop internationally com-

patible standards. This would save time and money, which would otherwise be invested in largely redundant work, serving to establish better international compatibility (HL7 Germany e.V. 2015), which is important for the full exploitation of the potential of mobile technologies. HL7 currently has four active working groups (HL7 2016) dealing with subjects of standards development for safe mHealth apps, programming interfaces for health information, security and privacy standards and SMS usage for health applications. IHE is presently developing transaction definitions to facilitate data exchange between mobile devices and existing databases (IHE 2016).

1.3.3 Organisational Structures

In the current legislation, some of the necessary processes, concepts and goals are defined ambiguously or deficiently, which can lead to significant problems regarding transparency, outcome measurement and project coordination. Insufficient ex-ante planning and preparation result in increased risks of cost and schedule overruns (Flyvbjerg 2014). Ideally, clear and binding interoperability catalogues, standards, and understandable definitions should be adopted prior to the development of concrete infrastructures and applications (e.g. electronic patient records). Since until now technological innovation cycles progress faster than standardisation processes, even in countries with advanced digital health systems, standardisation remains a major challenge (Anell et al. 2012, Barbarito et al. 2012, Boyle 2011, Chen et al. 2014, Chevreul et al. 2010, Edwards et al. 2010, Lai et al. 2013, OECD 2013, Rice et al. 2013, Rolnick 2013, Steel et al. 2012, Strandberg-Larsen et al. 2007, Vuorenkoski et al. 2008). However, a benchmark of the European Commission clearly shows that Germany is below average in Europe in terms of the adoption of eHealth, which also includes the dimensions of infrastructure and integration (European Commission 2014).

The organisational structures should be arranged in such a way that they provide sufficient protection against the influence of individual interests and allow processes transparency. In this way, key players are not excluded from relevant development processes. If this is not taken under due consideration, socially inefficient outcomes, public mistrust, and reduced acceptance of results (Dixit 1998) can ensue. Specific precautions to improve supervision can help minimise these risks, including process transparency, and clear selection criteria for external consultants, as proposed by HL7 Germany e.V..

1.3.4 Learning Healthcare Systems

The potential of digital technologies should be exploited more fully for the purpose of research promotion. Extensive discussions are currently taking place about how the future of "learning healthcare systems" could be designed. Health apps can be seen here as a key pillar for obtaining information (Foley and Fairmichael 2015). The development of a roadmap for the transformation of the German healthcare system towards a learning organisation structure based on emerging digital infrastructures is recommended.

1.3.5 Reducing the "Digital Divide"

The "digital divide" of the usage potential of modern health technologies among citizens must be reduced. Owning a smartphone alone is not sufficient to take meaningful advantage of health apps. Rather, the existence of a sufficient infrastructure, as well as digital and health literacy (i.e. the ability to use digital applications properly and to critically evaluate health information) is of importance. The provision of equitable access to eHealth solutions and the promotion of eHealth literacy of German citizens are societal tasks that require the concentrated efforts from various ministries, public authorities, and organisations.

2 Opportunities and Challenges

See Chapter 4. Health Apps and Challenges. Bertolt Kuhn & Volker E. Amelung

The range of health apps is as varied as the users and their needs. The description of characteristic functions is just as difficult as defining the role that they can or should take in healthcare. Whether an app does more good or harm is difficult to judge.

Apps related to health should be consistently differentiated according to the purposes, applications and user groups. This would make the classification easier as to whether they are rather marketing tools with no added value for the health of users or whether they bring a real benefit. Methods and tools are needed to distinguish between the useful and the less useful offers.

2.1 Having Potential, But Lacking Evidence

The potential is established in particular with regard to possible cost savings and quality improvements. Health apps are potentially suitable to support the self-management of chronically ill patients effectively and to increase adherence and compliance. The use of apps in lifestyle-induced diseases such as diabetes mellitus (type 2) is at the forefront here. A high therapy adherence, which can be supported by apps, can prevent costly treatments and hospitalisations in many chronic illnesses (Robert Koch Institute 2015).

For persons who are hard to reach using conventional ways, the different functions and application areas of apps have the potential to provide support for their respective problems. Especially for persons with various disabilities and functional limitations (health) apps can open up new possibilities and help them cope better with the handling of their health problems and live more independently. This does, however, require an appropriate, e.g. barrier-free, design and a general good usability of the apps. It is also important that the apps address the different needs of the patients, as well as their requirements. Currently, apps that adequately implement this are rare. Usually, it is more a case of addressing the needs of the general public. To improve the situation, incentives should be created for manufacturers to provide high-quality services for smaller groups as well, for which, however, a big benefit can be expected.

Another area where health apps can probably play an important role is providing care for the rural population. Here, apps, together with other telemedical offers, can potentially help tackle supply bottlenecks. It may be helpful to build on the experiences of other countries that have healthcare systems that are similarly well developed as the German one.

In the long run, however, the potential of apps for healthcare can only be exploited if they can be integrated in the existing care and compensation systems. Apps for which this is not possible will not be able to establish themselves within care processes.

Although the description of the potentials is plausible, there is little scientific evidence available, for example, in the form of study results, which may be due to the fact that classical scientific practices are not very suitable in this case. The required (longer) period of investigation is often diametrically opposed to the high development dynamics of the apps to be evaluated and the mobile devices they run on. This explains why there is so far only little evidence for the cost-reducing potential of health apps.

2.2 Promoting Effectiveness and Expanding Infrastructure

The usability of health apps mentioned above is a decisive factor (Mival and Benyon 2015; Dyer et al. 2012), which can contribute to the effective use of health app in healthcare. Improving and expanding telemedical infrastructures and ensuring good compatibility between the various systems are equally important.

To transfer the potentials of mHealth and health apps into reality, the development and expansion of telemedicine infrastructures should be encouraged. One possible contribution would be to clarify the remuneration of healthcare providers in telemedical care projects. Here, representative organisations of healthcare professionals, as well as the various professional societies are called on to get involved. Once the remuneration is cleared up, health apps will be employed more actively by doctors. As a result, this may also mean that patients use appropriate apps more often – and to the benefit of their health. The health professionals can set an example at this point.

2.3 Ensuring Quality and Security

The search for high-quality health apps is a challenge for both patients and health professionals. Without assistance, it is difficult for them to orient themselves. High-quality (health) apps that provide valid information and fulfil their purpose reliably and safely are more the exception than the rule.

Laymen and professional users are barely familiar with the criteria that they can apply to identify secure and useful offers. This can be remedied through appropriate guidance, which will be addressed in more detail in other parts of the report. Framework conditions and quality requirements that can be used to evaluate the quality and security of apps should be formulated in these guidance documents.

It would also be desirable to determine the specific needs already in the planning phase before starting the implementation. Furthermore, the targeted user groups such as patients and healthcare professionals should be involved in the planning and the implementation. This is the only way to develop health apps, which meet the demands of those who will use them later.

3 Areas of Application

3.1 Health Apps in Prevention

See Chapter 5. Health Apps and Prevention. Maria Rutz, Darja Kühn & Marie-Luise Dierks

Health apps can potentially be used in primary, secondary and tertiary prevention[2]. To achieve lifestyle changes, there are already many offers in the form of "lifestyle" apps. These can raise their users' health awareness, primarily in relation to physical fitness and weight loss. In the context of these apps, the largest proportion of studies that were identified in the literature dealt with prevention. Here, there was evidence that the use of apps can have a positive impact on the increase in physical activity, changing diet and weight control (e.g. Lubans et al. 2014, Glynn et al. 2014, Nollen et al. 2014, Carter et al. 2013). For other areas, studies are lacking which securely demonstrate the positive impact of apps, for example, for informing about cardiovascular risk factors or the prevention of cancer. The fact that the use of apps in the prevention decreases over time has not been sufficiently investigated yet. The majority of studies do not collect data about precise disease-specific outcomes, making it difficult to assess the results.

3.1.1 Benefits of App-Based Prevention

The main benefit of apps is to create low-threshold access to health-promoting services. Thus, preventive lifestyle changes can be initiated for many persons at an early stage, without the health system having to get involved. Also, due to the technical possibilities, apps have the advantage of being able to make recommendations based on the most recent data (Neubeck et al. 2015).

To make best use of health apps in prevention, the preferences of users must be precisely evaluated and the users must be enabled to identify effective apps. Both users and experts should be involved in the development of apps to review the evidence and to recognise risks at an early stage.

3.1.2 Improving Access to Prevention

Studies should pay more attention to different settings and different social groups when evaluating the efficacy of apps in prevention. It should be investigated how to reach persons with an increased risk of disease and low health literacy in a more efficient way. Costs incurred in the context of using apps must not lead to disadvantages for specific population groups. Alternative models for prevention are to be developed here.

In future, an evaluation and structuring of the existing apps and studies in relation to evidence, use and effects is advisable, as till now, the main focus was on single apps and apps new to the market . There is still a lack of long-term scientific studies that evaluate the requirements for apps to make an effective contribution to prevention.

The use of wearables is increasing. The continuous recording of data via wearables can be used in the prevention of diseases (O'Reilly and Spruijt-Metz 2013). However, it must also be studied to what extent self-tracking can intensify fears of illness ("cyberchondria").

The range also includes apps that encourage behaviour that is harmful to health (Crane et al. 2015). Strategies for dealing with this type of "malware" must be found as well.

3.2 App-Based Diagnostics and Treatment

See Chapter 6. Health Apps and Diagnostics and Treatment. Maria Rutz, Darja Kühn & Marie-Luise Dierks

Health apps are offered and used to support diagnostics and treatment, including rehabilitation. Their benefit is that (any) information can be collected, accessed and visualised at any place and at any time (Meng et al. 2015). This can allow for swift decisions, optimised treatments and cost reduction. For patients, it is convenient to be able to communicate with their attending medical and care staff regardless of time and place (Ritchie 2013). For doctors, when providing care, mobile applications offer new means to obtain up-to-date information about their patients. When using apps in the context of telemedicine care concepts (particularly in dermatology, cardiology and radiology), it is important to check the validity of the diagnoses and to respect the legal requirements (the ban on a solely remote treatment of patients, without any direct contact having taken place beforehand).

[2] Primary prevention involves among other things education about health risks or early detection screening procedures with the aim of preventing the emergence of diseases (BMG 2015 and GKV Spitzenverband 2014, page 15 or Article 20 of the Fifth Book of the Social Security Code (SGB V)). Secondary prevention deals with screening for diseases in the context of known risk factors. The aim is to initiate the "earliest possible treatment" (BMG 2015) or intervene in diseases in early stages (GKV Spitzenverband 2014). Tertiary prevention attempts to reduce the consequences of an existing illness, to largely avoid their aggravation or to prevent relapses (BMG 2015). Rehabilitation is also part of tertiary prevention (GKV Spitzenverband 2014).

3.2.1 Use by Lay People and Professionals

Apps for diagnosing diseases are predominantly used by medical professionals, whereas apps for treatment are used by doctors and patients alike. In the literature, wearables and health apps used in the care of patients with neurological disorders are strongly represented (e.g. Lopez et al. 2014, Zhao et al. 2015). The majority of apps for use by lay people and professionals deals with skin diseases and cardiovascular disorders. Health apps have the potential to be useful tools in healthcare because they support the presentation of medical findings, communication processes, and the aggregation of data, thus speeding up the process of making a diagnosis.

3.2.2 Success Factors

For users, more easily communicating with their physician and the corresponding practice is of primary importance (e.g. Ritchie 2013). They also have high expectations regarding safety and want app recommendations from doctors or health insurance providers. Collaboration between app developers, users and those providing treatment is necessary, as is regular adaptation of the user interface to the needs of the users.

3.2.3 Functional Areas in Diagnostics and Treatment

Many apps have identical (isolated) feature sets (Arnhold et al. 2014). For the future, a combination of various functionalities in one app (awareness-raising and education, support for lifestyle changes, strengthening health-promoting behaviour, management of diseases, etc.) would be useful. In particular as regards the data transfer, it is not entirely clear whether apps fully exploit the existing technical possibilities. Further studies on the quality of data transmission, as well as the advancement of the technology, are necessary.

Health apps for supporting self management are gaining importance (e.g. Chomutare et al. 2011, Baron et al. 2012). These apps are meant to accompany persons of all ages in their daily lives and improve communication between healthcare providers and patients. This therapeutic field of application has been studied frequently. It remains to be seen whether the use of apps can lead to sustainable improvements of self-management. Especially elderly persons, who are often unfamiliar with the technology, may not be able to take full advantage of the benefits apps offer for healthcare. The competences of elderly people should be promoted and the apps themselves developed so that they can be used by elder generations. Valid evidence is lacking as to the extent to which apps are already integrated in healthcare and what the potentials for elderly persons are. Also, existing apps often do not fully implement existing guidelines for self-management.

The healthcare for migrants represents a further area of application for apps. Communication between doctors and migrants can be facilitated with the help of translation apps. However, the preferences of the migrants should still be systematically recorded to be able to provide better healthcare services.

3.2.4 Motivation Through Apps

The wearable market is expanding, but there are only few studies dealing with the use of this technology for diagnostics and treatment. It can, however, be assumed that the costs incurred and possible measurement inaccuracies can be an issue.

Little is known about reward systems that lead to an improvement in the adherence by using health apps in therapy. It is also unclear what factors need to be taken into account for apps used in the short term, and what factors are important in the context of long-term use. There is just as little information on the use of multiple apps for the same purpose, so-called app-hopping. No information on this topic was found. Therefore, studies on the consequences of and dealing with different pieces of information should be carried out here. It is also important that, in the context of diagnostics and treatment, there are few gender-specific apps or apps intended for socially disadvantaged groups in the context of diagnostics and treatment and that apps for these groups, just like various fields of application (settings), are not adequately considered by existing studies.

In principle, apps offer the chance for participation and patient involvement. They can support different phases of the care process within healthcare. Transparency must be established both with regard to app development (Cantudo-Cuenca et al. 2014) and intended use. Users must be able to clearly identify the objectives and intended areas of application of the apps. To avoid incorrect uses, the limitations of the apps should be clearly specified. In cases of damage due to incorrect implementation, the issues need to be resolved in a rapid and professional manner.

3.3 Health Apps in the Context of Research

See Chapter 7. Health Apps in the Context of Research. Urs-Vito Albrecht, Ute von Jan, Oliver Pramann & Heiner Fangerau

Apps are becoming increasingly popular in the research context. In addition to the evaluation and validation of existing app-based interventions and treatment pathways in healthcare, they create new possibilities for data collection in clinical trials. Here, apps can potentially help save resources and provide assistance in acquiring data.

3.3.1 Possibilities of Apps in Research

Integrating apps into clinical research can bring benefits for all involved. For the participants, for example, the number of absolutely necessary visits to the study centre can be reduced when using an app-based study design. Both researchers and participants benefit from the largely simple and convenient data acquisition. This can lead to a more complete data pool, which is also easier for researchers to evaluate. In addition, with the help of research apps, parameters can be recorded both selectively and continuously, which could not have been recorded – or at least not to the same extent – through conventional approaches (Albrecht, Pramann and von Jan 2013). There are also advantages with regard to the recruitment or inclusion of larger study populations. Using app-based approaches, it is also possible to recruit participants who would have been excluded earlier, e.g. due to geographical distance. Caution is advised in this approach, however, in terms of attention to inclusion and exclusion criteria, if the app used represents the sole route of contact to the study centre (Albrecht and Pramann 2014).

3.3.2 Challenges of App-Based Research

Irrespective of the chosen research approach – be it an evaluation of existing solutions or app-based data collection – a number of challenges must be considered if apps are to be accepted in this context. This affects both basic scientific and technical areas, but in particular data protection, data security and ethical as well as regulatory matters (Friend 2015, Albrecht, Pramann and von Jan 2013, Reiss 2013, Albrecht and Pramann 2014). Already at the planning stage, it should be assessed whether an app should be classified as a medical device, with all ensuing consequences. However, both the developers and researchers involved are often not sufficiently aware of this. Guidance documents should be developed that serve as the basis for future developments.

3.3.2.1 Standardisation of Research on and with Apps

Designs of studies performed on or with apps are usually just as little standardised as the apps used in them. Apps with the sole purpose of acquiring data, without having an influence on it, will pose little risk. However, when dealing with the evaluation of app-based healthcare approaches, the comparability of the results to other studies suffers. Given the fact that apps have to demonstrate their effectiveness and applicability if they are to become an integral part of medical care, this is not acceptable. It would be desirable to apply standards similar to those used for pharmaceutical products here as well (Wetter 2016).

For apps used as a research tool (dedicated research apps), there are publications on approaches to help with standardisation. For example, the "ResearchKit" (McCarthy 2015, Albrecht 2015) presented by the Apple Group in 2015, like other libraries following the same thoughts, offers standardised components, which can be used to design relevant apps. These libraries must, however, still establish themselves and some are only available to certain user groups or limited to a single mobile platform.

3.3.2.2 Scientific Standards and the Everyday Reality of Users

The much-requested evidence of the effectiveness need not be identical to the actual benefits of health apps or the measures concealed behind them. The result of the evaluation depends on the selected study design and the setting in which it is used. An existing "evidence" for a measure or an app means that a statement can be made that meets the scientific quality criteria of objectivity, reliability and validity. Many details of what can be transferred to the user's real life, however, typically differ from the standards used in the study. On the other hand, a lack of evidence does not fundamentally exclude the usefulness of the app.

3.3.2.3 Ensuring equal access, avoiding bias

When employing scientifically sound methods, there should be awareness of factors potentially leading to a bias even before the study starts. In particular, for app-based studies that usually take place under conditions that are hard to control, there may be a selection bias for the sample if certain population groups are under-represented. This bias can result from the exclusion of those who have no access to the proper equipment or are simply unable or unwilling to use the technology (Kim, Briley and Ocepek 2015, Smith 2013). If there is no guarantee that the broadest groups of people can participate, the results of the study are difficult to transfer to the population as a whole. Ideally, adequate "participation equality" (here in terms of representativeness and equal participation) can be achieved by ensuring access to the necessary equipment. Measures that allow those who are not familiar with an app to use the required technologies (digital literacy) might also prove helpful.

Considering the currently available evidence (or its lack), a further analysis of what is going in the world of app-based medical research is urgently needed. There are only few studies that comprehensively assess both the positive and negative potentials, including ethical aspects, of using mobile technologies in research.

In future, given the continuous technological advancement various adjustments will be needed to ensure the necessary balance between technical innovations on the one hand and their scientifically correct and ethical use on the other hand, in the area of research.

4 Risks of Health Apps

See Chapter 8. Health Apps and Risks.
Urs-Vito Albrecht

Undisputedly, the use of apps in all health-related areas carries a number of risks in addition to the obvious opportunities. These can relate both to an application's efficacy (including any adverse effects) or the lack of thereof (not achieving the desired effect). Both can have lasting consequences on health – especially for the sick persons. Overall, the question is which damages and hazards exist and what risks can be derived from them for the users, and possibly for their environment.

4.1 Risks, Hazards, Potential Damage

For any use of health apps, hazards must be eliminated and risks minimised to reduce potential damage. The scientific literature describes different hazards that may arise from the use of apps in the context of health. While data protection violations are often reported there has been so far little evidence of real damage to health caused by health apps. According incidents make their way into the daily press if at all.

However, with the necessary caution, conclusions by analogy can be drawn based on experiences in the field of medical devices. Hazards may thus arise from a number of sources: on the one hand, malfunctions (Kemnitz 2007) can potentially trigger damage both in the apps themselves (incorrectly implemented functionalities) and in the devices on which they are used. On the other hand, incorrect or misguided use (use-error, see Israelski and Muto 2012), for example due to design problems of the app in question, can be problematic. This can also occur if the app is used without being suited for the respective use case or if the requirements of specific usage scenarios were not given due consideration.

More importantly, apps bundle information and make it accessible. Therefore, misinformation distributed via an app represents a relevant source of danger. If the information is used as a basis for decision-making, incorrect diagnoses (in terms of an incorrect assessment of the disease), as well as potentially incorrect treatments (incorrect treatment as unsuitable, not sufficiently effective, or excessively performed treatment) can be the consequence. Both incorrect diagnoses and mistreatment pose a significant damage potential for the health of users.

4.2 Risk Reduction

Various measures are conceivable in order to effectively counter the risk potential of health apps, which apply at different stages of the life cycle of an app and for various players. Scientific monitoring should be considered in implementing these measures where possible and is to be promoted accordingly. In order to be effective, these measures must also consider the nature of the dynamic and liberal market. They must also be fast and easy to implement and it must be possible to customise them to allow for the required flexibility.

4.2.1 Development

Already during the planning and development of software, manufacturers must perform a risk analysis to identify and eliminate any hazards in advance. To do this, best-practice methods should be used for developing software. Instructions can be found in the relevant standards. The development process must be based on common quality criteria and respect the principles of quality assurance. It is important that the manufacturers provide transparent information about their products. This includes communication on hazards and risks as well as actual damages. This can be done at a low-threshold in the product information in the app stores and the apps' accompanying web pages.

4.2.2 Openly Communicating Adverse Events

In order to be able to soundly assess potential hazards of health apps, however, is not enough to only name potential risks. Additionally, any incidents that have occurred must be disclosed. However, proof for such incidents is rarely found. Evidence of damage caused by apps is very rare in the literature; often, there are at best fragmentary outlines of potential hazards. Rather, for actual problems, there are product recalls by the manufacturer to be found (e.g. Pfizer 2011). Nevertheless, the risks of apps are hardly smaller than for other measures in the context of health. Here, establishing a low-threshold vigilance system similar to the EU's RAPEX system should be encouraged, in which messages about potential and actual damages and adverse effects can be collected at a central location and provided to the public. The reported information can come, for example, from the manufacturers, but also the users, who can report events directly. It would be desirable for providers of distribution platforms (app stores) to be involved in the process, as well, as part of their efforts to improve the quality of the health apps they offer. On the part of the distribution platforms, mandatory quality requirements, which – among other aspects – deal with content-related quality, would also be helpful. The internal review processes already existing on many platforms should be improved to respect these aspects.

4.2.3 Measures by Operators

Operators of health apps are required to take appropriate measures to minimise risks arising from the use of health apps. In cases of use in a professional environment, it is important to create appropriate guidelines and process specifications (Pramann and Albrecht 2014). This may include, for example, binding hygiene standards for use (cleaning/disinfection of the devices being used), but also processes that serve to protect patient data on the devices (security guidelines for work equipment or private devices used for work). Providing training and information is also to be encouraged, and this aims at increasing sensitivity in this context. This does not only relate to lay users, but also to persons in various professional contexts. Many users are not aware of potential risks and hazards associated with the use of mobile devices and apps. Therefore, care must be taken to communicate these to all involved. Awareness-raising campaigns aimed at the general public, but also at individual user groups as well as providers and developers of apps, can prove helpful. The greater the understanding of those involved regarding the risks resulting from the use and the ensuing (medical, legal and ethical) consequences, the sooner will measures that are recommended or mandated either on an organisational level or by the authorities find acceptance.

5 Health Apps and Ethics

See Chapter 9. Health Apps and Ethics. Heiner Fangerau, Maria Griemmert & Urs-Vito Albrecht

Technology-based measurements are not a new phenomenon in medicine. People have been watching their bodies with its functions, limitations and diseases since time immemorial and documenting what they have measured. The currently booming sector of mobile health applications is based on this need. However, the new technology has some peculiarities such as the extensiveness and ubiquity of the data collected, which necessitates not only a scientific and legal discussion of its opportunities and risks. Rather, a debate about the moral dimensions of mHealth applications seems necessary. Just as for health and technology, there are also opportunities and risks to consider on a moral level. In connection with mobile applications that are used in the context of health, there are many different aspects of medical ethics that need to be discussed.

A variety of approaches dealing with questions related to ethics and the use of mobile health applications is described in the literature. These reflect the diversity of app concepts, areas of application and user groups and the associated opportunities and risks on the one hand and the shifting focus between addressees resp. users of apps as well as providers or medical care on the other hand.

The primary issues are the conflicts of objectives when using mHealth. In particular, privacy and transparency, but also control and autonomy are to be considered in particular in this case. Further ethical issues relate to

questions of fairness in the use, availability, the participation opportunities, and also the effects the new technology has on the self-perception of doctors. Often, the challenges are discussed in a general way, e.g. in relation to patients (data), healthcare professionals and researchers or the requirements for closely connected application cases, such as people infected with HIV (Labrique 2013, L'Engle et al. 2015, Pérez et al. 2015) or psychiatric patients (Chan et al. 2015, Glenn and Monteith 2014a, Jones and Ashurst 2013, 2015 Olff, Seko et al. 2014).

5.1 Privacy and Transparency

Extensive recording of data (as made possible via mobile solutions) offer great opportunities for improving care. This is among other things a question of transparently using large amounts of data to the benefit of many. On the other hand, in the context of ethics, data protection and data security, summarised using the keyword "privacy", are issues that are equally reflected in the legal and technical discussions. Interest in transparency can be explained by the optimisation of healthcare based on the maximum information possible. The interest in privacy is based on experiences of stigma, fears of suffering disadvantages and the interest in autonomy in relation to one's own sensibilities as well as findings associated with an individual. The two values are diametrically opposed and yet users want to achieve both goals, resulting in a paradoxical situation (Bueschel et al. 2014). Especially in this context and referring to established standards of research ethics, a critical issue is that for mHealth based approaches anonymity is difficult to implement; it is therefore recommended to keep data transfers to third parties to a minimum. In light of prevailing standards, providing comprehensive information about the data collected and how they can be used should be a matter of course. (Carter et al. 2015).

5.2 Ethical Principles

Key principles of medical ethics are the imperatives to do no harm, to observe the autonomy of patients, which for example includes doctor-patient confidentiality, always to act for the benefit of the patient, and to distribute healthcare services as fairly as possible. Discussions about the potentials for resolving disparities in the provision of healthcare service are associated with the latter aspect. Additionally, mHealth based solutions make it possible to more easily reach patients in sparsely populated regions as well as disadvantaged groups of persons (Nasser and Trevena 2015, Nurmatov et al. 2014, Gordon et al. 2015).

The criteria of reliability, quality, correctness and minimum susceptibility to error – also taken up in other parts of the present work – can be seen as a minimum requirement from an ethics point of view, and these criteria can be deduced from the imperative not to harm the patient and the requirement to act for his benefit.

5.3 Responsibility

Points previously mentioned in the context of the use of technology and its resulting potentials and risks should also be kept in mind. In particular, the loss of interpersonal aspects is up for discussion. There are fears that, when using technology, personal communication between those involved might be impaired and that there could be a loss of appreciation and respect (Fangerau and Badura-Lotter 2014). Furthermore, there is the question of liability if medical technology fails. Responsibility may lie with the doctor, the developer or the patient. The potentials for misuse of the technology that were already touched upon in the context of transparency and privacy are also once again up for discussion, in particular if there is a suspicion that these new solutions for medical problems may be linked to the interests of third parties, such as insurance companies or the pharmaceutical industry (Fangerau and Martin 2014).

The frequently expressed demand for greater control of mHealth applications follows from this discussion. The protection of users against possible risks should be a top priority. However, it appears the ethical discussion is not yet at an end. An investigation that assesses and categorizes the ethical "problems" of health apps with respect to their risk potential appears to be necessary as well as promising, since risk-related argumentations can be found at all levels (medical, technical, social, legal, in terms of data protection, on an interpersonal level, etc.). At the same time, current ethical debates on mHealth should make use of past experiences with technology developments in medicine and should also take previously successful problem-solving strategies into account. Some of the questions currently being discussed are similar to ones that have already been raised in previous contexts. It is important to identify the peculiarities of new developments in mHealth. An analysis of new risk structures in terms of their premises, their explicit or implicit values and influencing factors and dependencies seems expedient for application-oriented research in the context of mobile health apps, particularly when the aim is to take stock of the ethical situation on a comprehensive comparative scale.

At the same time, guidelines for the development, recommendation and use of health apps should be considered, which focus, among other things, on factors such as user autonomy and security, ruling out discrimination and stigma, and good scientific practice (Albrecht and Fangerau 2015).

6 Law

6.1 Health Apps and Data Protection

See Chapter 10. Health Apps and Data Protection. Oliver Pramann

In addition to the moral questions relating to data protection and privacy that were briefly sketched in the previous section, from a technical as well as legal perspective, both data protection and privacy remain points of special interest. It is unclear whether the relevant data protection requirements are always complied with, which, due to the sensitivity of information, is of particular relevance for health apps. In Germany, data protection and privacy rules are established in Article 2 (1) of the Federal Data Protection Act in conjunction with Article 1 (1) of the German Constitution[3] (Grundgesetz) and the right to informational self-determination derived from the verdict of the Federal Constitutional Court (BVerfG) on the Population Census Law (the so-called census verdict4).

The key regulations are the relevant European data protection guidelines and the Federal Data Protection Act (BDSG) in Germany, as well as important special regulations in the tenth book of the social code (SGB X), the Telemedia Act (TMG) and the Telecommunications Act (TKG). Either a legal element of legitimacy from the fundamental Federal Data Protection Act or a more specific regulation, where applicable, is required to collect, process, and use data lawfully. The consent of the respective right holder is also possible here (Baumgartner 2013, paragraph 225) if a statutory provision does not preclude this. The data protection law applicable in Germany places special demands on information and consent, which are also to be observed for apps.

Apps in particular are often offered in an international context and the storage, use, and processing of data gathered does not always take place in Germany. If the parties are based in Germany and the data are used domestically, the provisions of the Federal Data Protection Act shall apply. If the provider of the app is located in another EU Member State or within the European Economic Area (EEA), the so-called registered office principle according to Article 1 (5) clause 1 of the Federal Data Protection Act (BDSG) shall apply and the respective data protection law applicable there shall apply. Only when the provider is based outside the European Union or the EEA, once again Article 1 (5) clause 2 BDSG shall apply if data is collected in Germany via an app (Gola, Klug and Körffer 2015, paragraph 29 cited according to Baumgartner 2013, paragraph 198). However, it is questionable here to what extent German data protection law can also in fact be effectively enforced with respect to app providers outside the EU in the latter case (Baumgartner 2013, paragraph 201).

For users located in Germany, full implementation and enforcement of German data protection requirements guarantee appropriate data protection. In addition to the aforementioned problems in the context of international app offerings, in particular the abuse and the failure to implement the requirements can be problematic.

It should be noted that comprehensive data protection legislation exists in Germany. In addition, harmonisation of regulation in Europe will also be implemented shortly in the form of the General Data Protection Regulation. Particularly health data are legally privileged. If the legal provisions are in connection with the use of apps, the existing level of protection can be transferred to the area of apps. Shortcomings are to be due to the manner of implementation by the providers, the lack of transparency in obtaining informed consent and providing adequate information, as well as the sensitivity of users in connection with privacy issues. The protection of minors in relation to data utilisation is problematic, irrespective of whether they are adolescents that have the necessary cognitive capacity and are able to give consent. In effect, when using apps, it is possible for minors to grant consent to the collection, processing and utilization of data, without their legal guardians having consented to this or the minors themselves being able to understand the scope of their decision (Buchner 2006, paragraph 247; Baumgartner 2013, paragraph 326). This does not constitute valid consent. It is questionable whether the data are still being processed and used.

A consistent implementation of the existing regulations and the creation of appropriate clarity and transparency in information and consent would promote the exercising of the individual right to informational self-determination. Whether official regulations for providing information and obtaining consent can contribute

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[3] The Constitution for the Federal Republic of Germany in the version published in the Federal Law Gazette Part III, outline number 100-1, as most recently amended by article 1 of the law of 23 December 2014 (Federal Law Gazette I p. 2438).

4 BVerfG, judgment of 15 December 1983 – 1 BvR 209/83, 1 BvR 269/83, 1 BvR 362/83, 1 BvR 420/83, 1 BvR 440/83, 1 BvR 484/83, BVerfGE 65, 1-71.

to appropriate transparency is open for discussion. Because apps are commonly distributed via app stores, a joint commitment, and, if necessary, an obligation for the app stores to review apps should be discussed.

6.2 Health Apps as Medical Devices

See Chapter 11. Health Apps as Medical Devices.
Oliver Pramann

Health apps can be classified as medical devices in the legal sense, depending on the intended use stated by the manufacturer. Whether an app is a medical device or not depends on whether it meets the definition of Article 3 No. 1 MPG. This is always the case if the app is used for diagnostics or treatment. If the manufacturer rules out a medical purpose for apps that include corresponding features, this must be clearly and unequivocally identifiable (Gassner 2015, Possienke 2015, Pramann and Albrecht 2015, Heimhalt and Rehmann 2014a, Heimhalt and Rehmann 2014b, Pramann and Albrecht 2014, Backmann 2011). However, whether there is a distinct medical purpose is an individual decision, and this also has an impact on the exclusion of medical purpose. There are already various guidelines available to manufacturers and users (BfArM 2015), including those issued by the authorities, but these are not binding and may not apply to individual cases.

Till now, a number of questions regarding the regulatory requirements for health apps are still open. Apps that are medical devices fit into the existing framework of the medical devices law. Their safety can thus also be verified based on the existing rules. In practice, however, making a distinction between apps that are subject to the Medical Devices Act and those where this is not the case, proves quite difficult (Pramann and Albrecht 2014, Pramann and Albrecht 2015). There is legal uncertainty here, in particular for manufacturers and users. Although it is generally possible for the authorities to audit the manufacturers and to intervene if necessary, depending on the circumstances, it is impossible to do so consistently.

With regard to the problem of delimitation, binding administrative regulations with delimitation criteria and examples would make a contribution to the harmonisation of the rulings in this new field. As it essentially comes down to the purpose when making a distinction between apps that are covered by the Medical Devices Act and those that are not, it could be considered to make it obligatory to prominently and visibly state the purpose of health related apps. This obligation could be integrated into consumer protection laws, as these would also apply to apps not covered by the Medical Devices Act.

Apps that are medical devices are, like other medical products, divided into risk classes according to potential risk (Annex IX of Directive 93/42/EEC). They will often be assigned to class I if they have a correspondingly low potential risk. It remains to be seen whether group of apps will evolve that exhibit a higher potential risk, which could justify the general classification in a higher risk category. For apps that can give laymen a self-diagnosis and treatment, for example, it can be discussed to what extent they should generally be allocated to a class higher than class I. This would result in the necessity to involve a notified body, which would provide a further inspection instance for assuring safety, independent of the manufacturer and in compliance with the necessary harmonised standards.

7 Health Apps in Statutory and Private Health Insurance

See Chapter 12. Health Apps in Statutory and Private Health Insurance.
Ines Aumann, Martin Frank & Oliver Pramann

Health insurance funds and health insurance companies are crucial to the reimbursement of costs for the care of insured persons. As a (complementary) form of care, mHealth is relevant to the insurance providers.

An analysis of the market situation was conducted in terms of apps, the reimbursement possibilities as well as the effects and incentives for statutory and private health insurance (systematic literature search, Internet research, quantitative survey of insurance companies). The offer and the financing of apps in the German health insurance system were examined more closely. As there is only little evidence in relation to the different questions that were examined, the analysis can only be seen as a first step to tackling the topic of "apps and health insurance funds/providers". It is therefore necessary to perform further scientific studies to discuss the use of apps from the perspective of the insurance providers.

Even now, some health insurance funds/providers already offer their own apps with different functionalities, in particular with the aim of gaining/retaining customers and reducing administrative costs. The results of the survey of health insurance companies showed that future apps should contain a number of functions that – if sustainable use takes place – provide those insured with added value. For insurers, the importance of apps will grow continually. For patients, using the apps on offer can contribute in particular to an optimisation of self-management. This can lead to improvements regarding health-conscious behaviour, adherence and compliance, thus resulting in reduction of costs for healthcare in the long term.

7.1 Service Applications, Health Promotion and Prevention in the Foreground

From a competitive perspective, both service applications and apps for health promotion and prevention are particularly valuable. For insured persons, service apps can represent a low threshold offer, which they can use to obtain information about health topics in a simple manner. With the help of targeted offers for health promotion and prevention through apps, health insurance funds/providers want to catch the attention of young persons and win them as customers. The actual health benefits of such prevention apps, however, remain unclear and should be evaluated further.

7.2 Little Interest in Apps for Diagnostics and Treatment

To date, apps for diagnostic or therapeutic purposes are not of great interest to the health insurance companies. There are, however, financial incentives to offer or develop apps when implementing new forms of healthcare and in the context of selective contracts. This can save costs and ensure the provision of care to those insured. To make it possible for the insured to successfully use apps in the context of diagnostics and therapy, professional advice and guidance are needed. In this regard, apps are no different from other medical services. Especially in the area of diagnostics and treatment, a high quality of apps in terms of operability, comprehensibility and privacy is of particular relevance. For each individual app, its medical benefits must be evaluated. Therefore, the few existing apps are offered through special forms of healthcare or selective contracts of individual health insurance providers. To make use in standard care possible and to achieve an improvement in healthcare in this way, the question of reimbursement by the payers must be solved (Kaufmann 2014, Zuck, 2014, Rübsamen 2015). To that end, clear criteria and requirements should be formulated for possible reimbursement of the costs, and these specifically need to take possible damages and risks resulting from the use of apps into account. It is also questionable to what extent the efficacy of apps can be evaluated in currently typical clinical trials or whether special requirements must be formulated for apps. For manufacturers and providers of apps to be used for diagnostics or therapy, it is important that there is transparency and security as regards reimbursement of the costs in standard care. Equally, for apps outside the context of diagnostics and therapy, the reimbursement process should also be uncomplicated and easily accessible, in order to make sure that the apps are put to use. It is essential to determine whether and, where appropriate, how the reimbursement processes for an implementation of apps in standard care need to be adapted. It must still be observed whether conventional services will be strongly substituted with apps, which could lead to a discrimination of certain population groups such as the elderly and non tech-savvy persons. In addition to the questions of the reimbursement of costs, the quality of apps offered is also paramount. Currently, the quality of apps is very heterogeneous. Therefore, it is important to develop generally valid quality criteria that facilitate safe use.

7.3 Data Acquisition and Processing with Apps – a Domain of Private Health Insurance

With regard to the use and the offer, there is primarily a difference between the statutory healthcare and private healthcare when it comes to data acquisition. For statutory health insurance, the possibilities of the use of data are legally very severely restricted and pose a problem with respect to a breach of privacy by insured persons. Statutory health insurance has so far mainly used apps in bonus programmes. To that end, however, it must be demonstrated that savings are actually facilitated and efficiency increased through the use of an app. So far, there is little evidence in this regard, which must be seen critically. In addition, the financial impact of such bonus programs should be limited so that there is not a general increase in premiums. These additional offerings must also continue to support themselves. Private health insurance can theoretically use the data collected with the help of apps for the calculation of premiums adequate to the risk. Currently, this is not yet the case. Health-conscious behaviour is only rewarded in the context of incentives (e.g. Generali 2015), much like in statutory health insurance. However, the development of regulatory requirements is necessary. An indirect pressure to use appropriate apps could follow if a non-use has a negative impact on the calculation of premiums. To date, limited access to health-promoting or preventative apps (e.g. because of age or illness) still has no direct negative effects because the financial consequences of non-use of bonus programs or incentives are low.

In statutory health insurance, there are already strict privacy rules with regard to the collection and retention of social data (Article 284 (1) SGB V). However, the data protection obligations and their compliance by third parties, such as intermediaries or app providers, are not entirely clear. In private health insurance, the data protection requirements are based primarily on the Federal Data Protection Act. Now it is a case of improving transparency with regard to data collection, use and storage, and establishing clear regulations.

8 Guidance

8.1 Orientation for Users of Health Apps

Among the variety of products, users of health apps are facing the challenge of identifying a suitable and trustworthy one.

See Chapter 13. Orientation for Users of Health Apps. Urs-Vito Albrecht

8.1.1 Identifying a Trustworthy App

Users should consider different aspects in order to identify trustworthy and high-quality offers. Already before installing an app, they have to identify who is responsible for the app and what functions it contains. The limits of the application should also be made clear here. An app should only be used if it is recognisably up-to-date. The quality of the information provided in the app can be estimated, amongst other things, on the basis of the qualification of the manufacturers. Only if it is shown that an app has been implemented by qualified persons according to the state of technology and medicine, should it be trusted. Users also need to be sure the app has been designed for the intended purpose of their application and for them as a target group (Albrecht, Noll and von Jan 2015, Yasini and Marchand 2015, Voas 2003, Ben et al. 2010).

As regards health apps, the presence of a full privacy policy is particularly important. The privacy policy should inform the user in plain language about the data processing behaviour of the app. Users should also critically question the permissions requested by an app. Once an app demands more access than is necessary, it should not be used. Apps that have a clear medical purpose based on their functions and the description by the manufacturer and are thus to be regarded as a medical device, but are not marked as such, should not be used.

Quality labels can also speak for the quality of an app if the underlying testing method is validated. The same applies to studies that have been conducted according to scientific standards. Often, apps are evaluated by other users, and the results of the reviews are presented in the app store. These reviews can serve as a first assessment of the quality, but should not significantly affect one's personal assessment.

8.1.2 Current Guidance and Evaluation Platforms

The existing guidance and platforms for users are very heterogeneous in their objectives, business models and concepts (see, for example, afgis 2012, Albrecht, Pramann and von Jan 2015, imedicalapps.com, app-check the "Centre for telematics and telemedicine GmbH" (ZTG), "HealthOn-app honour code" (HealthOn)). To date, none of the various methodological approaches (codes, seals of quality, reviews by professionals or lay users) have prevailed for the detection of quality and trustworthiness. The transparency of providers in relation to quality criteria and verification processes and the internationality of the app market represent further problems. There is still no comprehensive and at the same time valid guidance for assessing the trustworthiness of health apps.

8.1.3 Developing Appropriate Tools

The development of decision aids for users is very important due to the prevalence and increasing use of health apps. All players (manufacturers, users, initiatives, certifiers, etc.) must be integrated to achieve a maximum credibility and acceptance. Several steps are necessary for the development of guidance. The exchange between players (communication) and the agreement on quality and trust aspects (consensus about elements of trusted software) are the top priority. Then, strategies must be developed for the production of high-quality and trustworthy products and their safeguarding or approval procedures/review. In addition, transparency in relation to the products and their manufacturers must be promoted. Finally, targeted information must be made available to all participants (information/education) and incentives must be created for the implementation of quality-assured and trusted applications (promotion). The industry has a particular responsibility at this point. The aim is to promote certification initiatives that offer valid and transparent test procedures in order to provide users with trusted guidance.

This process should be conducted by a superior, economically independent state initiative. Continuous updating and adjustment of the measures is necessary because the app market develops very fast. Therefore, a comprehensive and up-to-date review of all health apps by an official body is not realistic. Rather, multiple approaches should be pursued to meet the different needs arising from different usage types and locations.

8.2 Guidance for Professional Users of Health Apps

See Chapter 14. Orientation for Professional Users of Health Apps. Tobias Hartz, Ute von Jan & Urs-Vito Albrecht

Health apps are used in the treatment context. It is expected that patients will increase demands on their suppliers (Behrends et al. 2015). Healthcare providers will also want to make fuller use of apps. In other countries, mobile devices are already widely spread across all layers of the population and there is a high utilisation rate of apps in the health context both on the part of doctors and patients. Here, healthcare providers are already increasingly giving app recommendations to their patients (Zhang and Koch 2015).

8.2.1 Offers for Professional Users

The trend towards using apps in the healthcare sector is also increasingly detected by software providers. There are tools and applications for patients that not only allow them to research information on health issues and to capture and manage data in the health context, but also send these to their doctors in a manner compliant with data protection regulations. Apps with a specific focus on medical professionals are also being increasingly used. In addition to health apps, where special requirements in the area of health have already been considered during their development process, there are also apps that were originally focused on a different application area (Johnston et al. 2015, Drake et al 2016, Giordano et al. 2015). Nevertheless, these apps can also perform in the health sector if used appropriately.

8.2.2 Guidance is Necessary, But Rarely Available

Policy recommendations for health professionals that consider handling of apps or provide help on how to recommend apps to patients are virtually non-existent.

Therefore, mandatory criteria, e.g. in the form of official guidelines, are needed, which providers can use to ensure the legally safe and ethically acceptable use of health apps. These have to answer a number of questions.

Both with regard to their own use and in relation to possible app recommendations, it is important that healthcare providers recognise that not every app is appropriate for the medical context. This is also in their own interest: if healthcare providers use an app that is not explicitly intended for the particular purpose, in case of doubt they can be made liable for any damage, over which they have no influence (e.g. malfunctioning of the app). However, professional users are rarely able to carry out a comprehensive assessment of the suitability of apps in general or those for specific application areas. In addition to possible uncertainties from a technical perspective and in terms of content, sensitive data are handled in a far less critical manner, as a rule. Potential damage and risks that may arise thereby seem rather theoretical and not immediately ascertainable for many users. The direct and immediate consequences are rarely visible to them. Especially for apps that are used for communication or data exchange, there still appears to be insufficient awareness of the problem. Partly enthusiastic reports about the use of messenger apps and services for communication about patients can also be found in the literature (Johnston et al. 2015, Drake et al 2016), but usually without going into further detail on data protection concerns.

8.2.3 Identifying Quality, Utilising Opportunities and Minimising Risks and Dangers

Based on their own skills, healthcare professionals can only judge the quality, suitability, and trustworthiness of an app to a limited extent. However, healthcare providers must ensure when using apps in a professional context that the apps are suitable for the respective area of application (healthcare, research and education and training). In addition to the technical assessment of the medical content, which can be performed throughout, the assessment of technical, legal and ethical aspects, which are also relevant, is normally more difficult without further assistance. For meaningful and legally compliant use of apps in a professional context, an intensive consideration of the opportunities and risks of apps in healthcare and the provision of appropriate recommendations, guidelines and structures for the healthcare providers is required. For example, they should only use apps with a medical purpose if they carry a CE mark (Royal College of Physicians 2015).

Appropriate recommendations on the use and an assessment of the respective app also only work if healthcare providers can rely on the information available on the respective app, which, in addition to information from the manufacturers, may include certificates, labels, etc. The heterogeneity of the current situation was outlined in the previous section. The aforementioned creation and promotion of certification initiatives with valid and transparent review processes may prove helpful.

When using apps, compliance with the applicable laws represents another essential aspect for healthcare providers. In this context, it must be ensured that the regulations on remote treatment, according to which

no exclusive treatment via communication media may be carried out (Bundesärztekammer 2015), are complied with, and it must also be ensured that a doctor treats the patient in person. An app can therefore only ever represent a complement to the treatment and healthcare concept; otherwise, liability issues may arise. Difficulties may also be experienced with regard to long-term monitoring of patients, since it cannot be assured that a doctor who knows the person concerned personally constantly evaluates the data and can intervene in case of doubt.

Even though apps with their original purpose lying outside of the medical area (for example messenger apps) are often used to exchange information with colleagues about common patients, this can prove problematic. The aspects of data protection are the top priority here. In this regard, for many providers of communication apps, the requirements of the health area do not fit with the regulations contained in the terms and conditions. In addition, a corresponding use often takes place on private devices. A clear separation between professional and private use is desirable, but often difficult to enforce in practice when using mobile devices. Also, the data security and data integrity of apps can be endangered by using other apps on the same device. There is a threat of legal consequences if patient data inadvertently falls into the wrong hands. This problem should be drawn to the attention of both doctors and other healthcare professionals.

8.2.4 Measures That Can Offer Guidance

Overall, the promotion of awareness-raising campaigns seems meaningful in addition to the design of guidance. Policy makers should support this idea and push for more firmly integrating information about the adequate use of apps into the education and training of healthcare providers. The improper use of apps should be more strictly regulated. At the same time, alternatives must be created and relevant projects must be promoted. In general, tools such as guidelines, recommendations and certificates, which serve a better evaluation of apps, must be promoted or provided by decision makers.

8.3 Guidance for Manufacturers of Health Apps

See Chapter 15. Orientation for Manufacturers of Health Apps. Matthias Brönner, Sven Meister, Bernhard Breil & Urs-Vito Albrecht

A cornerstone for a safe and successful use of health apps is that all quality-relevant aspects have already been considered adequately during their planning and development. However, some developers overlook the potential health risks of their apps as well as relevant regulatory aspects for health apps in particular. The development of health apps of suitable quality must be guaranteed by the manufacturers irrespective of whether the app is a medical device or not. Manufacturers, from large companies to small start-ups and amateur developers, do not necessarily have the required knowledge. Guidance as issued by the Federal Institute for Drugs and Medical Devices (BfArM 2015), the American FDA (2015) or the German Association for the Electrical Engineering and Electronics Industry (ZVEI 2014) and the Düsseldorfer Kreis (2014) can give a first reference for health apps.

8.3.1 Various Quality Standards

Though the question of criteria for a high-quality app is relevant, it is also difficult to answer. The concept of quality in itself leaves much room for discussion. In the industry, quality is understood as the degree of compliance with clearly defined requirements. The requirements may vary depending on the industry sector. In general, quality is an obvious part of each product. The concept of quality and quality management processes form the starting point for production in a variety of industry sectors. In the field of health apps, this obviousness is not present to date.

8.3.1.1 The Fundamentals of Quality-Assured Development

Beyond the usual standards of software development, as set out for example in the ISO 250xx series of standards, there is currently little clarity about which quality criteria should be taken into account in the first place. The fundamental quality criteria in the ISO 250xx of series of standards include, for example, considering the intended functions (functionalities) and those relevant to the user, a suitable ratio of performance and cost (efficiency) and also the possibility of cooperation, exchange and/or coexistence with other products (compatibility). Moreover, the operation should be easy and special needs (for example accessibility) should be considered. Similarly, reliability and the implementation of adequate data protection and data security measures are required. In addition, maintenance and care should be implemented in such a way that the services of the software are available continuously (maintainability). Furthermore, it should be possible to adapt to different conditions of use (portability). ISO 9001 defines quality standards in particular with regard to the

quality management of products and services. Nevertheless, the definitions and standards of quality described here are rarely considered in the implementation of apps if the market is to be looked upon in its entirety.

8.3.1.2 Additional Requirements in the Context of Health

A number of additional requirements should be considered in the health sector. The priorities are user security in relation to the physical integrity and/or health of users, but also the integrity of the data collected and processed. If risks cannot be ruled out, safety mechanisms are to be implemented, for example, by informing users of a possible problem using alarm or notification functions. Also, transparent information of all players about the risks is to be ensured, especially regarding those which cannot be turned off or for which no adequate safety measures are (or can be) taken. Compliance with existing legal requirements, which in the area of health go far beyond those in software in general, must be guaranteed. For apps that are represented as medical devices, there are requirements in the form of IEC 62304 and other standards that need to be considered as regulatory minimum. It is unclear, however, whether the requirements described herein are sufficient. In addition, there is a potential for conflict between the understanding of quality presented here and that in ISO 9001. Whereas ISO 9001 specifically looks at the satisfaction of explicitly expressed and implicit requirements or needs of relevant stakeholders (customer satisfaction), the safety of patients is in the foreground in ISO 13485.

8.3.2 Development of Health Apps on the Life Cycle

The planning must consider the relevant processes for project management and define to which processes the software development itself is subject. Different models are available. These differ essentially in their methods that range from linear processes through interactive iterative structures to agile models. In addition to the implementation, the planning is also subject to an iterative and incremental approach, in which problems can be responded to rapidly.

In the design phase, the considerations and findings of the planning are transferred to software architecture and software design, which should serve as a blueprint for the subsequent implementation. In this step, it is defined how flexible the future product will be and how it can be integrated into the IT landscape in the context of other information systems. The specification of the data model, the product features and the interfaces are important aspects in the design phase.

The implementation phase serves as a gradual transformation of the planning towards a functional app. New insights inevitably arise here that were not or could not be adequately addressed in the planning phase because the context framework conditions at the time of the planning may have changed prior to the development (e.g., operating system updates, new frameworks or equipment, etc.).

As stated in the planning and requirement analysis, the app is subjected to various tests. These take place on various levels and with various means. These could include a (automated) testing of the source code of the app or product features based on defined test cases as usability tests. The results of the tests are to be documented.

Once the road has been paved from the requirements through the design and implementation to the verification and validation of a software system, the provision of the software for external users follows. If the health app is a medical device, this is to be equated with the placement of the product on the market. Corresponding apps may only be published if there is a valid CE marking. The “essential requirements” according to 93/42/EEC must be met for this purpose, namely a conformity assessment procedure has been completed and a declaration of conformity has been issued prior to the publication. In addition, first-time placement on the market is to be reported to the German Institute of Medical Documentation and Information (DIMDI).

On the other hand, the maintenance aims to ensure the continuous operation of the app. On the other hand, it is about extending the functionality and reducing sources of error and barriers. The existing quality should at least be retained. As a rule, an improvement is achieved. Any irregularities discovered must be documented and communicated, as well as the measures taken to remedy the situation. For a medical device, it is in particular important to identify the possible risks of a medical device placed on the market (for example, based on customers’ feedback) and to respond to this. Even if the Medical Devices Act does not provide a specific definition of the term “risk”, adverse effects, reciprocal influences, malfunctions, technical defects, contraindications, falsifications or other risks associated with medical devices, which are named in Article 31 of the Act in the regulations for medical device consultants, are to be documented. A respective legal procedure in

form of relevant reporting obligations of safety aspects is provided in the Order on the Recording and Assessment of, and Counteractive Measures for, Risks Linked to Medical Devices (Safety Plan for Medical Devices – MPSV).

8.3.3 The Intended Purpose Leads the Way

The intended purpose has a key role in all considerations. It can be considered the foundation of an app and is to be chosen carefully right at the start. An app receiving a relevant purpose only in the course of time can result in large costs. The purpose must be kept in view in all activities and also be communicated clearly and unambiguously to the users.

As the rapid development cycles and the sheer number of available apps hardly allow for a comprehensive quality control by third parties, manufacturers should disclose the quality criteria they use as far as possible so that users can inform themselves better and more easily.

The health app is only taken seriously as a tool in the context of health if it meets the quality requirements in relation to safety, usability, functionality and transparency. The quality-assured development is an essential component to offer applications that can be used with confidence in the health context. In the long-term, only the apps that also earn this trust will take precedence. If this subject is not consistently and adequately addressed, the sustainability of this technology is unlikely, as it will not be accepted by all of the players.

9 Fields of Action, Possible Actions and Players

To improve the overview and to provide a basis for future discussions, fields of action with action options and the players, which are or need to be primarily involved (from the author's point of view), are presented in a summarised form5. 64 specific options for action can be derived from the chapters (see table 2). These are assigned to nine fields of action: (a) organisation and infrastructure, (b) financing, (c) access, (d) ethics, (e) regulation, (f) research, (g) quality, (h) transparency and (i) information. The players are divided into nine groups: Federal Government / Federal States, stakeholders, manufacturers, providers, lay users, professional users, researchers, healthcare institutions and payers (see table 1).

For many of the listed options of action, several players need to be involved. To emphasise which player is seen primarily as the initiator of the respective course of action (from the perspective of the project team), in the table, the initiators (○) are differentiated from other relevant players. (●) If the costs of an action option can be attributed to one or more players, who are not simultaneously seen as the initiator of the option concerned, they are specifically marked (€). Depending on the chosen manner of implementing an action option that is not exhaustively described in this document these assignments may be subject to change.

Table 1: Overview of the players.

Player	Explanation with examples (not exhaustive)
Federal Government / Federal States	Political institutions on Federal and State levels (including the Federal Ministry of Health (BMG), state ministries of health, the Federal Institute for Drugs and Medical Devices (BfArM), the Federal Office for Information Security (BSI), the Federal Commissioner for Data Protection and Freedom of Information (BfDI), the Federal Centre for Health Education (BZgA), the Federal Government Commissioner for Patient's Affairs and Representative for Care).
Stakeholders	Stakeholders, associations, public law bodies (including the Aktionsforum Gesundheitsinformationssystem (afgis) e.V., the German Medical Association (BÄK), ZTG Zentrum für Telematik und Telemedizin GmbH, the German Dental Association (BZÄK), the German Disability Council (DBR), the German Federation for the Deaf(DGB), the German Hospital Federation (DKG), the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), the National Association of Statutory Health Insurance Physicians (KBV), the National Contact and Information Point For Encouraging and Supporting Self-Help Groups (NAKOS), the Private Health Insurance Association (PKV), the Federation of German Consumer Organisations (VZBV)).

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5 Our thanks to Tobias Hartz and Mrs Uta Hillebrand for assisting in the revision.

Continuation of Table 1

Player	Explanation with examples (not exhaustive)
Manufacturers	Persons and bodies responsible for developing the app (e.g. software companies, programmers).
Providers	This player can overlap with others. However, the actual provider through which a person can obtain an app (including app stores) is primarily meant in this context.
Lay users	Users who do not use an app in the professional context (primarily the health-conscious and patients).
Professional users	Healthcare providers who use the respective app in a professional context.
Researchers	Persons and institutions that look at the apps in a scientific context (including universities, colleges and other research institutions).
Healthcare institutions	Institutions that are involved in the direct care of patients (including hospitals, medical service centres, practices).
Payers	Parties carrying the costs for healthcare in its original sense (such as health insurance funds, health insurance providers, pension insurance).

Table 2: Overview of fields of action, options for action, and players.

		Fed. Gov. / States	Stakeholders	Manufacturers	Providers	Lay users	Professional users	Researchers	Healthcare institutions	Payers
(a) Organisation and infrastructure										
Situation: Organisational structures and existing infrastructure in the health sector are not adequately prepared for the additional requirements arising from the comprehensive use of mobile health applications (mHealth). Solutions are often only sought and implemented for issues limited to regional demands or specific topics.										
01.	Transformation of the German healthcare system towards a learning organisational structure.	○	●					●	●	●
02.	Making organisational structures and processes transparent and guaranteeing better protection against vested interests.	○	●					●	●	●
03.	Development of an adaptable eHealth/ mHealth strategy with a focus on functionality and results rather than on specific (isolated) solutions.	○	●					●	●	●
04.	Establishing eHealth and mHealth-based approaches more strongly and permanently in healthcare processes (e.g. via infrastructure measures, financial incentives).	○	●						●	€
05.	Expanding the necessary technical infrastructure to promote and ensure extensive care with (mobile and stationary) broadband Internet access.	○	●						●	●
06.	Clarifying definitions and – where necessary – establishing new standards or adapting existing standards (interoperability).	€	○	●	●	●	●	●	●	●
07.	Boosting internationalisation through development of internationally compatible standards.	○		●	●				●	●
08.	Identifying what is actually needed for providing care.	●	○	●	●	●	●	●	●	●
09.	Promoting the development of offers tailored to specific needs / requirements.	○		●	●					●
10.	Promoting health apps that have easily visible benefits and are user-friendly (market openers).	●	○							●
11.	Breaking down barriers for disadvantaged groups (e.g. through the availability of cheap basic tariffs, educational measures, technical equipment).	○	●	●	●		●	●		●
(b) Financing										
Situation: So far, in part due to unresolved financing, mHealth solutions and specifically adapted apps have not found their way into established care processes of the primary health market. Being a prerequisite for this, scientific evidence of the efficacy is not yet consistently available.										

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Continuation of Table 2

		Fed. Gov. / States	Stakeholders	Manufacturers	Providers	Lay users	Professional users	Researchers	Healthcare institutions	Payers
12.	Displaying ways of reimbursement of costs of apps / transfer to standard care.	●	●	●	●					○
13.	Formulating criteria and requirements for the reimbursement of costs, while taking into account possible risks.	●	○	●	●					●
14.	Clarifying remuneration of service providers in the context of (telemedical) healthcare.	○	●	●	●		●		●	€
15.	Creating financial incentives to improve cross-sectional care (hospital, rehab facilities, treatment at home, etc.) with the help of mHealth-based solutions.	○	●						●	€
(c) Access										
Situation: Due to a number of reasons, equal access across all population and user groups has so far not been guaranteed. Financial reasons (cost of purchasing devices and apps, expensive mobile tariffs), as well failure to respect special requirements (physically or cognitively handicapped groups, elder generations) are relevant here in addition to technical reasons (e.g. lack of infrastructure).										
16.	Promoting digital literacy and health competencies across all the population groups by expanding educational offers (from nurserys / schools to basic and advanced education and training and adult education) in all areas of life.	○								
17.	Promoting the development of offerings oriented around needs / requirements (apps, healthcare concepts, ...) to improve healthcare for otherwise difficult to reach groups that could disproportionately benefit from the implementation (rural population, rare diseases, ...)	○						●	●	●
18.	Promoting barrier free offers.	○	●		●				●	●
(d) Ethics										
Situation: Innovative technologies generate interest in many places. An ethical assessment of the potentials as well as hazards of the technology for the individual (loss of control of their own data, privacy, transparency etc.) and the community is necessary.										
19.	Discussion of equal access to care through mHealth.	●	○	●	●	●	●	●	●	●
20.	Discussion of protection of privacy and transparency.	●	●	○	●	●	●	●	●	●
21.	Discussion of autonomy and control.	●	●	●	○	●	●	●	●	●
22.	Ethical guidelines for developing, recommending and using health apps.	●	○	●	●	●	●	●	●	●
(e) Regulation										
Situation: Existing regulations for medical devices, data protection, etc., do not adequately respect the specific needs arising from the international character of the market for health apps. Due to the vast number of apps, a comprehensive review of health-related apps by the authorities is impossible. Measures which generally assist with gaining a better understanding of apps being offered or improve the availability of information needed for assessing health apps may be of help.										
23.	Developing a low-threshold vigilance system for keeping track of incidents or unexpected events (data protection, health risks, etc.) that can occur when using health-related apps.	○	●	●	●	●	●	●	●	●
24.	Strategically focusing on cross-application regulations.	○								
25.	Promoting the development of guidelines, policies, certificates, recommendations and structures to create transparency.	●	○	●	●					
26.	Implementing legally compliant criteria for the development, use and design of health apps.	○	●							
27.	Obliging the stores to critically assess fundamental aspects of quality for health related apps they offer.	○								
28.	Creating a legal obligation to clearly state the purpose of apps related to health.	○								
29.	Create binding administrative provisions that contain demarcation criteria and examples (e.g. with respect to distinguishing between apps that are medical devices and those that are not, risk classes) as a contribution to the harmonisation of rulings.	○								

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Continuation of Table 2

		Fed. Gov. / States	Stakeholders	Manufacturers	Providers	Lay users	Professional users	Researchers	Healthcare institutions	Payers
30.	Develop and label data protection standards.	○	●							
31.	Agreeing on the requirements / precise content of comprehensive information that must be provided with respect to data protection.	○	●	●	●	●	●	●	●	●
32.	Introducing or expanding an information obligation for manufacturers.	○								
33.	Develop and implement appropriate (organisational) measures to reduce the risks arising from the use of health apps.	●	●	●	○		●	●	●	●
(f) Research										
Situation: Like all other measures in the healthcare, health apps as well as app-based care and prevention concepts need to prove their effectiveness in scientific studies if they are to take permanent hold in healthcare. Currently, there is only limited comparability of studies that evaluate apps or make use of apps for research purposes. Often, due to the rapid development cycles of apps, there are only small studies of short duration with a rather narrow focus.										
34.	Promoting scientific evaluation of app-based concepts across various sectors.	○						●		●
35.	Where appropriate, app-based concepts need to be evaluated across sector boundaries.		●					○		●
36.	Promoting long-term (accompanying) evaluations of app-based concepts.	○								●
37.	Implementing long-term evaluations of app-based concepts.			●	●		●	○		
38.	Standardising studies with apps (to facilitate comparability).			●	●			○	●	●
39.	Scientifically evaluating the benefits of apps for various health-related areas of application.			●	●	●	●	○	●	●
(g) Quality										
Situation: In the context of health, only high-quality apps should be used to ensure safety and functionality. But consensus is currently lacking as to what lies behind the concept of quality. Coordination is necessary to be able to subsequently develop standards and assess "quality". On the one hand, appropriate steps need to be taken to promote the exchange between the different players to prevent that the needs of the users are not duly respected during development. On the other hand, care must be taken to ensure that fundamental quality aspects are known and are taken into account from the point of conception and over the period of development to the actual use.										
40.	Creating mandatory quality specifications for development.	○	●							●
41.	Establishing quality standards beyond the scope of the Medical Devices Act.	○	●	●	●		●			
42.	Develop participation formats for the various stakeholders.	○	●							
43.	Provide incentives and support for developing, using, providing and recommending trusted products.	○								●
44.	Promote initiatives for assessing the quality of apps.	●	○						●	●
45.	Develop general quality criteria for apps that may serve as guidance for manufacturers as well as users.	●	○	●	●	●	●	●	●	●
46.	Use quality-backed development processes, including risk analysis prior to implementation, in order to be able to reduce potential hazards.			○	●					
47.	Develop methods appropriate for evaluating the benefits of apps (e.g. for proving their efficacy for possible reimbursement of costs) in the context of healthcare research.	○						●		●
48.	Create a platform to facilitate exchange between developers and users (user groups) for better focused product development.	€	○	●	●					
49.	Involve the target group in the process of developing apps to make allowances for specific needs.			○						
50.	Develop strategies for developing trustworthy offers.	○	●	●	●	●	●	●	●	●
51.	Develop guidelines for manufacturers.	●	○		●					
52.	Promote the development of barrier-free services.	●	○							

Continued on the next page

Continuation of Table 2

		Fed. Gov. / States	Stakeholders	Manufacturers	Providers	Lay users	Professional users	Researchers	Healthcare institutions	Payers
(h) Transparency										
Situation: Adequate information that can support users and neutral third parties in assessing apps (content, functionality) is not provided by all manufacturers in a transparent manner. However, such information is necessary in order to be able to assess and evaluate applications and measures. If it is missing, both implementation and use are subject to uncertainty. A lack of trust in the technology may slow down or even impede its use despite its potential.										
53.	Disclose the quality criteria used.			○	●			●		
54.	Promote transparency of products / manufacturers.	○		●	●			●		
55.	Request additional information relating to the medical content and intended purpose(s) of the application from developers, as well as data protection with special reference to the requirements in a health context (similar to the age classification); transparent reporting about existing risks.	○			●					
56.	Encourage manufacturers to compile information about the entire manufacturing process from the very start of the development process, with data covering privacy aspects and the results of the risk analysis conducted prior to development. The information should be made available in a suitable location (stores) upon publication.	○			●					
(i) Information										
Situation: Users are not aware of all criteria necessary for assessing health apps. Both in private and professional context, health apps are often used unreflectingly. There are uncertainties about usage. This can result in risks both in terms of health and in terms of jeopardising sensitive personal or health-related information. This may also result in poor utilisation and a failure to exploit the full potential of the technology. Available sources of information about health apps are confusing, and of variable quality. Neutral and quality-assured services need to be developed to fill this gap. Guidance that lists and explains these services can be of help.										
57.	Develop tools such as guidelines, directives, certificates, recommendations and promote structures that enable care providers to select, use and recommend appropriate apps.	●	○							●
58.	Design guidance for lay persons (healthy persons, diseased persons).	●	○			●				●
59.	Educate manufacturers about regulatory requirements and prerequisites for approval.	●	○		●					●
60.	Design guidance for professional users.	○	●				●			
61.	Design guidance for researchers.	○	●					●		
62.	Facilitating orientation for users with respect to apps that are being offered (e.g. via clustering in stores if standards and process are valid).	○		●	●					
63.	Comprehensive information on data collected and its use.	○		●	●		●	●	●	●
64.	Provide comprehensive information to all (potential) stakeholders (including patients and possible professional users) about risks / hazards and (organisational) measures that contribute to their reduction or elimination.	○	●	●	●		●	●	●	●

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